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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
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EXAMINER

WEBB, GREGORY E

ART UNIT	PAPER NUMBER
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1796

NOTIFICATION DATE	DELIVERY MODE
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01/07/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/572,969

Applicant(s)

CLARK ET AL.

Examiner

Gregory E. Webb

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 3/21/06.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-24, 26-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _____ is/are rejected. 1-24, 26-27

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1) ☒ Certified copies of the priority documents have been received.

2) ☐ Certified copies of the priority documents have been received in Application No. _____.

3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 recites the limitation "the carrier." There is insufficient antecedent basis for this limitation in the claim. Furthermore, the applicant has previously required the composition to contain mineral oil. It is not clear if the composition further requires the vegetable as the term "carrier" is not defined in the independent claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-24, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gioffre (US4826676).

Concerning the dental use, Gioffre teaches the following:

The present invention relates in general to stable compositions for inhibiting **dental** plaque and calculus formation and more particularly to oral compositions containing a combination of active zinc in the form of zeolitic zinc ions and fluoride ions. The invention particularly relates to toothpaste compositions having the aforesaid characteristics. (*emphasis added*)

Concerning the preferred oil-based solvent and the vegetable oil, Gioffre teaches the following:

Suitable **vegetable oils** which may be used as the oil ingredient include **coconut oil**, cotton-seed oil, **sesame oil** and similar non-toxic **vegetable oils**, as described in Vegetable Fats and Oils by E. W. Eckey, Reinhold Publishing Corp., New York 1954. The **vegetable oil** is desirably selected to fall within the viscosity range of from about 100 to about 300 centipoises. A particular **vegetable oil** falling within this range is NEOBFE M-5, a fractional triglyceride of **coconut oil**. The **vegetable oil** ingredient may contain a minor amount of an anti-oxidant such as butylated hydroxyanisole or butylated hydroxytoluene, preferably in an amount ranging from about 0.1% to about 3% by weight, based on the weight of the **vegetable oil** employed. (*emphasis added*)

Concerning the thickener, Gioffre teaches the following:

The proportions of **gelling agents** or **thickeners** in extrudable effervescent compositions are sufficient to form an extrudable, shape-retaining product which can be squeezed from a tube and substantially maintain its shape thereon. In most cases, no more than 10% of **gelling agent** need be used and in most instances about 0.5 to 10% will suffice, and preferably about 1 to 5%. (*emphasis added*)

Concerning the mineral oil, Gioffre teaches the following:

Suitable oils for use in forming the present compositions include those which have viscosities ranging from about 100 to about 300 centipoises at 70.degree. F. Oils employable herein include **mineral oil**, light liquid petrolatum thickened to the necessary viscosity; and vegetable oils. A

mineral oil commonly employed in cosmetic compositions is Mineral Oil U.S.P. also known as Liquid Petrolatum U.S.P, **mineral oil** (heavy medicinal) white **mineral oil**, liquid paraffin, and heavy liquid petrolatum. Mineral oil U.S.P. is defined in Remington's Pharmaceutical Sciences, 13th edition, Mack Publishing Co., Easton, Pa. 1965 as "a mixture of colorless transparent, oily liquid, free or nearly free from fluorescence." It is tasteless and odorless when cold and develops not more than a faint odor of petroleum when heated. (*emphasis added*)

Concerning the preferred thickener, Gioffre teaches the following:

Illustrative of the polishing agents which may be employed in addition to the zinc zeolites are impalpable phosphates, e.g., dicalcium phosphate, tricalcium phosphate, insoluble sodium metaphosphate, magnesium phosphate, calcium pyrophosphate, **crystalline silica, colloidal silica**, aluminum hydroxide, alumina trihydrate, magnesium carbonate, calcium carbonate, bentonite, talc, calcium silicate, calcium aluminate, and aluminum oxide. The various polishing agents are described in standard handbooks such as Sagarin, "Cosmetics: Science and Technology," Interscience Publishers, Inc. (1963). (*emphasis added*)

Concerning the flavorant, Gioffre teaches the following:

Suitable flavoring or sweetening agents or mixture thereof, if any, may be employed in formulating a flavor for the effervescent compositions of the present invention. Examples of suitable flavoring constituents include **the flavoring oils, e.g., oils of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon, lime, grapefruit and orange...** (*emphasis added*)

5. Claims 1-13, 17-24, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gioffre (US4818518).

Concerning the preferred thickener and the silica, Gioffre teaches the following:

The dentifrice compositions of this invention include liquids and solids that may be proportioned to form a creamy mass of desired consistency which is extrudable from an aerosol or other pressurized container or a collapsible tube (for example aluminum). In general, the liquid vehicle in dental cream formulations will comprise glycerine, oils, propylene glycol, polyethylene glycol 400, etc. and the like, including suitable mixtures thereof. The total liquid content will generally be about 20 to 75 percent by weight of the dentifrice composition. A **gelling agent** in dental creams and gels may be employed, such as the natural and synthetic gums and gum-like materials, for example, Irish moss, gum tragacanth, methyl cellulose, polyvinylpyrrolidone, hydrophilic colloidal carboxyvinyl polymers

such as those sold under the trademark Carbopol 934 and 940, hydroxyethyl cellulose, Indian gum, acacia gums, agar, locust bean gum, synthetic silicated clays such as those sold under the trademark Laponite CP and Laponite SP, pectin and finely divided **pyrogenic silica**, sold under the trademarks CAB-O-SIL M5, SYLOID 244, SYLOID 266 and AEROSOL D 200. (*emphasis added*)

Concerning the preferred oil-based solvent and the vegetable oil, Gioffre teaches the following:

Suitable **vegetable oils** which may be used as the oil ingredient include **coconut oil**, cotton-seed oil, **sesame oil** and similar non-toxic **vegetable oils**, as described in Vegetable Fats and Oils by E. W. Eckey, Reinhold Publishing Corp., New York, 1954. The **vegetable oil** is desirably selected to fall within the viscosity range of from about 100 to about 300 centipoises. A particular **vegetable oil** falling within this range is NEOBFE M -5, a fractional triglyceride of **coconut oil**. The **vegetable oil** ingredient may contain a minor amount of an anti-oxidant such as butylated hydroxyanisole or butylated hydroxytoluene, preferably in an amount ranging from about 0.1% to about 3% by weight, based on the weight of the **vegetable oil** employed. (*emphasis added*)

Concerning the preferred surfactant, Gioffre teaches the following:

A dentifrice composition was prepared using the carbon dioxide-containing zeolite X of example 8. The dentifrice was prepared according to the procedure of example 4 using 41.04 grams of the carbon dioxide-containing zeolite X, 57.73 grams glycerol, 1.0 gram of sodium **lauryl sulfate**, 0.1 gram hydroxypropyl cellulose and 0.15 grams benzoic acid. A portion of the dentifrice was added to water and observed to provide an effervescent action. (*emphasis added*)

Concerning the mineral oil, Gioffre teaches the following:

Suitable oils for use in form dentifrice compositions include those which have viscosities ranging from about 100 to about 300 centipoises at 70.degree. F. Oils employable herein include **mineral oil**, light liquid petrolatum thickened to the necessary viscosity; and vegetable oils. A **mineral oil** commonly employed in dentifrice compositions is Mineral Oil U.S.P. also known as Liquid Petrolatum U.S.P., **mineral oil** (heavy medicinal) white **mineral oil**, liquid paraffin, and heavy liquid petrolatum. Mineral oil U.S.P. is defined in Remington's Pharmaceutical Sciences, 13th edition, Mack Publishing Co., Easton, Pa. 1965 as "a mixture of liquid hydrocarbons obtained from petroleum; a colorless transparent, oily liquid, free or nearly free from fluorescence". It is tasteless and odorless when cold and develops not more than a faint odor of petroleum when heated. (*emphasis added*)

6. Claims 1-13, 17-24, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene (US4689216).

Concerning the denture and the dental, Greene teaches the following:

These **hydrated silicas** have proved most useful in improving the sanguinarine uptake in dental plaque in toothpaste, however, they may similarly be incorporated into toothpowders, dental creams, prophylaxis pastes, and denture pastes and creams. (*emphasis added*)

Concerning the preferred oil-based solvent, thickener, preferred thickener and the silicas, Greene teaches the following:

To make toothpaste, the **hydrated silica** is dispersed in a dental vehicle which preferably contains a liquid which is water and/or a humectant such as **glycerine**, sorbitol, xylitol, **propylene glycol** or polyethylene glycol 400 (including suitable mixture thereof). The preferred amount of **hydrated silica** is about 2% by weight of the dentifrice, however, the effective upper limit for the **hydrated silica** can be as high as 99.97% by weight when the dentifrice is a tooth-powder. (*emphasis added*)

Concerning the surfactant, vegetable oil, preferred surfactant, Greene teaches the following:

The toothpaste can also contain surface-active agents, e.g. to achieve increased prophylactic action, assist achieving thorough and complete dispersion of the composition throughout the oral cavity and to render the composition cosmetically acceptable. The organic surface active material may be anionic, non-ionic, ampholytic, or cationic in nature, and it is preferable that the surface-active agent be deterative and impart foam. Suitable types of such surfactants are water soluble salts of higher fatty acid monoglyceride monosulfates, such as sodium salts of the monosulfated monoglycerides, or hydrogenated coconut oil fatty acids, higher alkyl sulfate, such as **sodium lauryl sulfate**, alkyl aryl sulfonates, such as sodium dodecyl benzene sulfonate, higher alkyl sulfoacetates, higher fatty acid esters of 1, 2-hydroxy propane sulfonates and the substantially saturated higher aliphatic amino carboxylic acid compounds, such as those having 12 to 16 carbons in the fatty acid alkyl or acyl radicals, and the like. Examples of the last mentioned amides are N-lauroyl sarcosine, and sodium and potassium and ethanolamine salts of N-lauryl, N-myristyl or N-palmital sarcosinate, which should be free from soap. (*emphasis added*)

7. Claims 1-24, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Maier (US6162449).

Concerning the denture and the dental, Maier teaches the following:

The cosmetic composition according to the present invention may also constitute an oral care preparation, e.g., a **dental gel**, a **denture** fixation aid or a tooth paste; a mucosal lubricant formulation such as a vaginal cream or gel; or an ophthalmological preparation such as eye drops; in which the glucan component B) may perform one or more of the following functions: *(emphasis added)*

Concerning the preferred oil-based solvent and the vegetable oil, Maier teaches the following:

Examples of such oils include aliphatic hydrocarbons such as **liquid paraffin, squalane**, vaseline and ceresin; **vegetable oils** such as **olive oil**, almond oil, **sesame oil**, **avocado oil**, **castor oil**, cacao butter and palm oil; animal oils such shark liver oil, cod liver oil, whale oil, **beef tallow** and butter fat; waxes including bees wax, carnauba wax, spermaceti and lanolin; fatty acids such as lauric acid, myristic acid, palmitic acid, stearic acid, oleic acid and behenic acid; aliphatic alcohols such as lauryl alcohol, stearyl alcohol, cetyl alcohol and oleyl alcohol; and aliphatic esters such as isopropyl-, isocetyl- or octadecyl myristate, butyl stearate, hexyl laurate, diisopropyl adipate or diisopropyl sebacate. *(emphasis added)*

Concerning the thickener, preferred surfactant, preferred thickener, and flavorant, Maier teaches the following:

	Ingredients:
	0.1-0.3% b.w. anti-
gingivitis/anti-bacterial agent, like Triclosan, 0.1-1.0% b.w. anti-caries	
agents, like sodium fluoride, sodium monofluorophosphate 1.0% b.w.	
gelling agents like carboxymethylcellulose, hydroxyethylcellulose or	
xanthan gum, 10-20% b.w. humectants, like glycerin, sorbitol 70% or	
propylene glycol, 15-20% b.w. abrasives like calcium carbonate, hydrated	
silica , dicalcium phosphate dihydrate or alumina, 0.1-0.2% b.w.	
sweetener like saccharin, 1.0-1.5% b.w. flavors like spearmint,	
peppermint, menthol or vanillin , 1.0-2.0% b.w. surfactants like sodium	
lauryl sulfate , sodium lauroyl sarcosinate or sodium lauryl sulfoacetate	
0.1-0.5% b.w. preservative like parabens q.s. colour ad 100 % water 5-	
10% b.w. .beta.-1,3-scleroglucan from Example 1.	
	<i>(emphasis added)</i>

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory E. Webb whose telephone number is 571-272-1325. The examiner can normally be reached on 9:00-17:30 (m-f).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gregory E. Webb
Primary Examiner
Art Unit 1796

gew